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09/648,958	08/25/2000	Peter Michael Edic	RD-27,641	6139

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GENERAL ELECTRIC COMPANY  
GLOBAL RESEARCH CENTER  
PATENT DOCKET RM. 4A59  
PO BOX 8, BLDG. K-1 ROSS  
NISKAYUNA, NY 12309

EXAMINER
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KIM, CHONG R

ART UNIT	PAPER NUMBER
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2623

DATE MAILED: 01/05/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/648,958

Applicant(s)

EDIC ET AL.

Examiner

Charles Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 9-18, 27-40 and 46-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 19-26 and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment and Arguments***

1. Applicant's amendment filed on October 2, 2003 has been entered and made of record.
2. The Applicant's arguments with respect to claims 1, 19, and 41 have been addressed below.

### ***Claim Objections***

The following quotation of 37 CFR § 1.75 (d)(1) is the basis of objection:

(d)(1) The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. (See § 1.58(a)).

3. Claims 1-8, 19-26, 41-45 are objected to under 37 CFR § 1.75 (d)(1) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery.

Referring to claim 1, the phrase "said selection portions" in line 6 lacks antecedent basis. It appears that the applicant intended the phrase to read "said selection portion". Similar objections are applicable to claims 19 and 41. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-8, 19-26, 41-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Referring to claim 1, the phrase “computing, using the spatial relationship between said pixels, a magnitude of an extensional feature of the imaged object based on the fit profile, said magnitude representing the extent of said feature in three dimensions” in lines 7-9 is not supported by the applicant’s specification. More specifically, the applicant’s specification is non-enabling in regards how the magnitude represents the extent of the feature in three dimensions. In view of the applicant’s specification (page 30), it appears that the magnitude of the extensional feature is the “residual **area** of the lumen” (second paragraph on page 30). This is further evident in claims 5 and 6, which recite that “the extensional feature is an area of a cross section of the interior region” (claim 5, line 6), and “the extensional feature is an area of a region defined by the cross section of the structure” (claim 6, lines 6-7). In this case, the magnitude represents the extent of the feature in two dimensions, not three. The Examiner was unable to find an instance in the specification that provides enabling support for the magnitude of the extensional feature representing the extent of the feature in three dimensions. The closest language in the specification to this feature appears to be on page 20, where it states “The one or more parameter values may then provide an accurate and repeatable estimate of an extensional feature (length, thickness, area, **volume**, ect) of the structural feature represented in the image”. In this case however, the applicant’s specification remains non-enabling, since it is unclear how

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the volume of the structural feature can be determined from an array of two-dimensional data (pixels) [claim 1, lines 2-3]. Similar rejections are applicable to claims 19 and 41.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-6, 23, 24, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 5, the phrase “the extensional feature is an area of a cross section of an interior region at the axial position on the specified axis” in lines 6-7 renders the claim indefinite because it is unclear how the extensional feature can be an area (two dimensions), if it represents the extent of said feature in three dimensions (claim 1, lines 8-9). Similar rejections apply to claims 23 and 44.

Referring to claim 6, the phrase “the extensional feature is an area of a region defined by the cross section of the structure” in lines 6-7 renders the claim indefinite because it is unclear how the extensional feature can be an area (two dimensions), if it represents the extent of said feature in three dimensions (claim 1, lines 8-9). Similar rejections apply to claim 24.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6, 19-24, 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wilting, U.S. Patent No. 5,757,877 ("Wilting") and Ning, U.S. Patent No. 6,075,836 ("Ning").

Referring to claim 1, Wilting discloses an image data analysis method, comprising:

- a. obtaining tomographic imaging data on an object, the imaging data comprising relative brightness (density) values over an array of pixels (col. 5, lines 42-55)
- b. fitting a profile from a selected family of profiles to a selection portion of the imaging data such that the profile conforms to the variation of brightness (density) values of the pixels in the selection portion of the imaging data (col. 6, lines 23-47 and figure 3)
- c. computing, using the spatial relationship between the pixels, a magnitude of an extensional feature of the imaged object based on the fit profile [col. 6, lines 54-57. Wilting explains that the width of the profile is computed to determine the dimension of the detail, wherein the dimension of the detail represents the diameter of the blood vessel, see col. 5, lines 60-64. Note that determining the diameter of the blood vessel is interpreted as being analogous to computing a magnitude of an extensional feature. The Examiner notes that the structure (blood vessel) that defines the extensional feature is assumed to have a tubular shape, wherein the cross

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section of the interior region of a tubular structure is circular. It is also noted that the diameter (d) of a circle is related to the area (A) by the relationship  $A=\pi*(d/2)^2$ . As noted above, Wilting explains that the magnitude of the extensional feature is represented by the diameter of the blood vessel. The Examiner notes that computing the diameter of a circle inherently determines its area, and vice versa. Therefore, Wilting's magnitude of the extensional feature represents the extent of the feature in two dimensions].

Wilting fails to explicitly disclose that the magnitude of the extensional feature represents the extent of the feature in three dimensions. However, Wilting explains that a three dimensional image of the object is formed by multiplanar reconstruction, wherein the reconstructed image is examined to determine measurements of the object (col. 4, lines 16-19). Therefore, it would have been obvious to modify the magnitude of Wilting so that it represents the extent of the feature in three dimensions, since the measurements of the object are determined from three dimensional data (reconstructed image).

The Examiner further notes that determining a magnitude of an extensional feature that represents the extent of the feature in three dimensions was exceedingly well known in the art. For example, Ning discloses that a magnitude of an extensional feature of an imaged object (blood vessel) is computed, wherein the magnitude represents the extent of the feature in three dimensions (col. 8, lines 32-38 and col. 19, lines 33-35).

Wilting and Ning are both concerned with determining measurements of a blood vessel from tomographic image data. Ning's method introduces no obvious artifacts, thereby enhancing diagnostic and therapeutic decisions (Ning, col. 3, lines 53-61). Therefore, it would have been

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obvious to modify the magnitude of Wilting so that it represents the extent of the feature in three dimensions as taught by Ning, in order enhance the diagnosis process.

Referring to claim 2, Wilting further discloses that the image data represents a cross section of the imaged object at a corresponding axial position on a specified axis (col. 6, lines 4-7), and the extensional feature is a spatial extent (diameter) of a structure (blood vessel) of the imaged object at the axial position on the specified axis (col. 5, lines 60-64).

Referring to claim 3, Wilting further discloses that the imaged object comprises an organ of a living subject and the structure is a blood vessel of the organ (col. 5, lines 53-64 and figure 2).

Referring to claim 4, Wilting further discloses that the living subject is a human patient (col. 5, lines 11-14 and figure 1) and the blood vessel is an artery (col. 7, lines 60-63).

Referring to claim 5, see the rejection of at least claim 1 above. Wilting further discloses that the image data represents a cross section of the imaged object at a corresponding axial position on a specified axis (col. 6, lines 4-7), wherein the selected portion of the image data represents a structure comprising a wall portion defining an interior region within the structure (figure 2).

Wilting also explains that the extensional feature is a diameter of the interior region defined by the cross section of the structure (col. 5, lines 60-64). However, Wilting fails to explicitly disclose that the extensional feature is an area of a cross section of the interior region at the axial position on the specified axis. The Examiner notes that the structure (blood vessel) that defines the extensional feature is assumed to have a tubular shape, wherein the cross section of the interior region of a tubular structure is circular. It is also noted that the diameter (d) of a



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circle is related to the area (A) by the relationship  $A=\pi*(d/2)^2$ . The Examiner notes that computing the magnitude of the diameter of a circle inherently determines its area, and vice versa. Therefore, it would have been obvious to modify the extensional feature of Wilting so that the extensional feature represents an area of a cross section of the interior region at the axial position on the specified axis; since the diameter and the area of a circle can be used interchangeably, in other words the area of the circle can be represented by its diameter.

Referring to claim 6, see the rejection of at least claim 1 above. Wilting further discloses that the image data represents a cross section of the imaged object at a corresponding axial position on a specified axis (col. 6, lines 4-7), wherein the selected portion of the image data represents a cross section of a structure of an imaged object (figure 2).

Wilting also explains that the extensional feature is a diameter of a region defined by the cross section of the structure (col. 5, lines 60-64). However, Wilting fails to explicitly disclose that the extensional feature is an area of the region defined by the cross section of the structure. The Examiner notes that the structure (blood vessel) that defines the extensional feature is assumed to have a tubular shape, wherein the cross section of a tubular structure is circular. It is also noted that the diameter (d) of a circle is related to the area (A) by the relationship  $A=\pi*(d/2)^2$ . The Examiner notes that computing the magnitude of the diameter of a circle inherently determines its area, and vice versa. Therefore, it would have been obvious to modify the extensional feature of Wilting so that the extensional feature represents an area of the region defined by the cross section of the structure; since the diameter and the area of a circle can be used interchangeably, in other words the area of the circle can be represented by its diameter.

Referring to claims 19 and 41, see the rejection of at least claim 1 above.

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Referring to claims 20 and 42, see the rejection of at least claim 2 above.

Referring to claims 21 and 43, see the rejection of at least claim 3 above.

Referring to claim 22, see the rejection of at least claim 4 above.

Referring to claims 23 and 44, see the rejection of at least claim 5 above.

Referring to claim 24, see the rejection of at least claim 6 above.

7. Claims 7-8, 25-26, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wilting, U.S. Patent No. 5,757,877 ("Wilting"), Ning, U.S. Patent No. 6,075,836 ("Ning"), and Troussel et al., U.S. Patent No. 5,218,534 ("Troussel").

Referring to claim 7, Wilting discloses that the image data represents a cross section of the imaged object at a corresponding axial position on a specified axis (col. 6, lines 4-7), and the selected family of profiles is a family of functions of an independent variable (col. 6, lines 23-47 and figure 3). However, Wilting and Ning fail to teach that the family of profiles is a family of functions of two independent variables.

The Examiner notes that a family of functions of two independent variables was exceedingly well known in the art. For example, Troussel teaches image data that represent a cross section of an imaged object at a corresponding axial position on a specified axis (col. 8, lines 9-15. Note that the plane  $z_i = \text{constant}$  is interpreted as a cross section of the object, see figure 3), wherein a family of profiles is a family of functions of two independent variables [col. 8, lines 9-67. Note that equation 17 is interpreted as a family of functions of two independent variables  $x$  and  $y$  ( $z$  is constant, as noted above)].

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Wilting, Ning, and Troussel are all concerned with analyzing cross sectional medical image data. Troussel's method provides an image of a 3D object under study which are more sharply defined and obtained more rapidly (Troussel, col. 1, lines 22-25). Troussel also explains that his method can be used for all types of processing of images or computed reconstructions (Troussel, col. 13, lines 37-41). Therefore, it would have been obvious to modify the family of profiles of Wilting and Ning, so that it is a family of functions of two independent variables, as taught by Troussel; in order to improve the accuracy of the diagnosis by providing an enhanced image of the object.

Referring to claim 8, Troussel further discloses that the family of profiles is a family of two-dimensional Gaussian profiles (col. 8, lines 9-22 and col. 9, lines 15-20).

Referring to claims 25 and 45, see the rejection of at least claim 7 above.

Referring to claim 26, see the rejection of at least claim 8 above.

### *Conclusion*

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The examiner can normally be reached on Mon thru Thurs 8:30am to 6pm and alternating Fri 9:30am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0377.

ck

December 17, 2003

  
AMELIA M. AU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2600